

Application No. 09/977,154
Amendment "E" dated January 12, 2005
Reply to Office Action of December 23, 2004

REMARKS/ARGUMENTS

Claims 1-18, 20, 21 and 23-34 remain pending in the application, wherein claims 1, 17, 21, 24, 25, 29 and 34 have been amended. No claims have been added or cancelled.

The Office Action objects to Figures 2 and 4 on the grounds that "reference character '22' has been used to designate different portions as the 'proximal section'". Applicant respectfully traverses this objection. The only difference between Figures 2 and 4 is that reference character 22 is shown on opposite sides of the proximal section 22. Because the interference screw 10 shown in Figures 2 and 4 has a tapered face 14, one side of the proximal section 22 is longer than the other side. Thus, when reference character 22 is placed next to the longer side as in Figure 2, it has a larger bracketed length than when placed next to the shorter side as in Figure 4. In view of this, Applicant respectfully requests reconsideration and withdrawal of this objection. This is a good faith response to the objection.

The Office Action rejects claims 1-18, 20-21 and 23-34 on the grounds that they "contain subject matter that was not disclosed in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention" (*i.e.*, the "distal threaded section having a length that is greater than the length of the proximal threaded section"). Preliminarily, Applicant respectfully submits that this rejection is inapplicable to claims 25, 33 and 34 as previously submitted since these claims did not include any language comparing the lengths of the proximal and distal threaded sections.

Whereas Applicant believes that the limitation quoted above is inherent, if not explicit, in the teachings of, *e.g.*, paragraphs [049], [050], [053], [054] and [054] and Figures 4, 6 and 7, Applicant has nevertheless amended the claims in order to recite language that is more clearly supported in the specification. Each of claims 1, 17, 21, 24 and 29 has been amended to recite the following:

~~the distal threaded section~~ interference screw having an overall length ~~that is greater than the length of the proximal threaded section~~ in order for the interference screw to apply force along a greater distance in the cancellous bone region compared to the cortical bone region,

(Emphasis in original to show claim amendments.) Support for this limitation is clearly shown in Figure 4, which shows an interference screw having an overall length (*i.e.*, from the proximal

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end to the distal end) in order for the interference screw 10 to extend further into the cancellous bone region 36 compared to the cortical bone region 34. This makes sense light of the teaching in paragraph [050] that "the cortical bone region of the tibia . . . is approximately 5 mm thick" and that an interference screw according to one embodiment has a length "within the range of approximately 35 mm to approximately 40 mm". This limitation is also inherent in Figure 6, which depicts an interference screw 60 having a distal threaded section 62 that is longer than the proximal threaded section 64, and also Figure 7, which depicts an interference screw 70 having a distal threaded section 72 that is longer than the proximal threaded section 74.

Each of claims 1, 17, 21, 24 and 29 has also been amended to recite the following:

the proximal and distal threaded sections being configured in order for the interference screw to apply less pressure against a soft tissue graft within the cancellous bone region compared to the cortical bone region.

(Emphasis in original to show claim amendments.) This limitation is supported practically verbatim in paragraph [055]. Further support is found in paragraphs [049] and [056]. The benefits associated with an interference screw that is able to apply greater pressure in the cortical bone region and less pressure in the cancellous bone region are described in paragraphs [049] and [056] (*i.e.*, secure compression of soft tissue graft against cortical bone region and less damage to, and quicker healing and bonding of, the soft tissue graft in the cancellous bone region).

The net effect of the amendments to claims 1, 17, 21, 24 and 29 is to emphasize that the claimed interference screws apply less force and along a greater distance in the cancellous bone region compared to the cortical bone region, thus distinguishing over the previously cited art in essentially the same manner as previously argued. In the event the PTO reinstates any of the previous rejections to any of claims 1, 17, 21, 24 and 29, Applicant reserves the right to reinstate the claims as previously amended and then argue that they do not claim new matter, particularly in view of Figures 6 and 7, which clearly show embodiments of interference screws in which the distal threaded sections (62, 72) are longer than their corresponding proximal threaded sections (64, 74). Moreover, Applicant points out that the proportions shown in Figures 6 and 7 can, in fact, be relied on to support a claim limitation because they are not found in a prior art document and because they are, in fact, drawn to scale. See MPEP § 2125 (which only applies to drawings in the prior art).

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The Office Action rejects claims 25 and 33 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,589,246 to Weiler et al. and claim 34 under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,360,448 to Thramann in view of U.S. Patent No. 6,387,129 to Rieser et al.¹

Claim 25 was amended to claim a method in which the interference screw applies "force along a greater distance in the cancellous bone region compared to the cortical bone region". Support for this limitation is clearly shown in Figure 4 (*i.e.*, the interference screw 10 extends further into the cancellous bone region 36 compared to the cortical bone region 34). Weiler et al. neither teaches nor suggests the use of an interference screw that is able to "apply a greater compressive force against the soft tissue graft in the cortical bone region of the bone tunnel and a lesser compressive force against the soft tissue graft in the cancellous bone region" and also "apply force along a greater distance in the cancellous bone region compared to the cortical bone region". Nor is this combination of features inherent in the use of the Weiler et al. screw. Whether the Weiler et al. screw is able to "apply force along a greater distance in the cancellous bone region compared to the cortical bone region" depends both on the length of the screw as well as the thickness of the cortical bone region. Since neither is disclosed in Weiler et al., it is just as likely as not that the Weiler et al. screw is a cortical fixation screw of the type disclosed in Rieser et al. (*i.e.*, having a length so as to provide mainly cortical bone fixation). Because an allegation of inherency can only be supported if the device in the applied art "necessarily" provides the claimed feature, rather than possibly or probably, Applicant submits that claim 25 as amended is neither anticipated by nor obvious over Weiler et al. MPEP § 2112.

With respect to claim 34, Applicant reincorporates by reference the Declaration of Hugh S. West, Jr., M.D. under 37 C.F.R. § 1.132 and the comparative study submitted previously, which are objective evidence that the claims are non-obviousness over U.S. Patent No. 6,387,129 to Rieser et al. It therefore follows that modifying a device according to Rieser et al. would not yield an obvious device since the interference screw of claim 34 has been objectively shown to have surprising and unexpected results relative to the Rieser et al. device.

Notwithstanding the foregoing, Applicant has amended claim 34 in order to recite an interference screw comprising "a single continuous thread extending between the proximal and

¹ Because Weiler et al. and Rieser et al. are only citable under 35 U.S.C. § 102(e), Applicant does not admit that these references are in fact prior art but reserves the right to "swear behind" one or more of Weiler et al. and Rieser et al. in order to remove them as a reference.

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distal ends". Support for this limitation is found in Figure 1. In the embodiment cited in the Office Action, the interference screw does not have "a single continuous thread extending between the proximal and distal ends". Threads 7a and 7b are separated by an intermediate section 8 that is not threaded and that constitutes a necessary feature of that embodiment. "[I]ntermediate section 8 has a surface layer of porous bone in growth material 6 for permanent fixation of the screw to the bone." Col. 5, lines 42-43. Eliminating the intermediate section 8 comprising bone in growth material 6 would render this embodiment unsuitable for its intended purpose and would therefore not be obvious as a matter of law. *See* MPEP § 2143.01. For at least this reason, Applicant submits that claim 34 is patentable over the combination of Thramann and Rieser et al.

In view of the foregoing, Applicant believes that the claims are presently in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application, may be clarified through a telephone interview or that can be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 12th day of January 2005.

Respectfully submitted,



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